Translation of Counterstatement of Maiwald & Partner GbR of 11 July 1997

File No.: P 44 47 287.0-41
CEVC, Gregor
Opposition of ROVI GmbH

EXHIBIT C

In response to the Notification of an Opposition of the German Patent Office dated 6 March 1997 and the letter of Opposition of 6 February 1997 enclosed therewith:

I. Requests

1) It is requested to reject the Opposition of the Opponent ROVI GmbH against German Patent DE 44 47 287 as inadmissible in form of an intermediate decision.
2) In case the request under 1) will not be granted, it is requested to reject the Opposition in its entirety as unfounded.
3) In case the requests under 1) and/or 2) may not already be granted in written proceedings, an Auxiliary Request for fixing a date for oral proceedings is made herewith.

II. Admissibility

According to § 59 I 4 German Patent Law, the reasons in an opposition procedure have to be substantiated, i.e. it is necessary that the facts justifying the opposition have been stated within the opposition period. The opposition is only considered as sufficiently founded if the Patentee and the Patent Office are enabled by the reasons of the opposition, without any further examination on their own, to verify the presence of the asserted opposition ground (see GRUR 1972, 592, 595 "Sortiergeräte"; GRUR 1987, 513, 514 "Streichgarn"; GRUR 1988, 113, 115 "Alkyldiarylphosphin"; GRUR 1988, 364, 366 "Epoxidations-Verfahren").

WM:NH:sc

The granted claims clearly show that the invention relates to liposome-like preparations, which are able to transport active agents into and through a permeability barrier, for example skin. According to the invention, this is achieved by adjusting the amount of surface-active substance.

In contrast to the prior art, the amount of surface-active substance is chosen in such a way that it is less than 0.1 mol % of that amount, at which the point of solubilization or saturation of the preparations is reached, i.e. at which the preparations would dissolve, or where the addition of further surface-active substance would reach the saturation limit.

Although the person skilled in the art would expect that a lowering of the amount of surface-active substance would lead to an increase in stability and a decrease in ductility, an optimization of the penetration capability through barriers like skin is still achieved according to the invention. As a result, droplets are able to penetrate through constrictions for which they are actually too large by one order of magnitude, so that the person skilled in the art would not expect this behaviour due to the high stability and stiffness which one would actually expect.

The Opponent requests to revoke the patent in its entirety, but he misses to substantiate it, by going into the features of the independent claims 1 and 22 and the dependent claims of the patent, individually.

The Opponent states in general *that the features A and B, which form the generic terms of the independent claims 1 and 22, have been taken from D1* (cf. 5, second paragraph).

However, the Opponent does not provide any statements which enable anyone to finally judge these assertions without any investigation on his own, with the cited prior art of D1-D5 at hand.

For example, the Opponent fails to indicate at which part of D1 one can learn that the carrier substance should comprise at least two (physico-chemically) different components (feature B).

The same is true for feature C that at least two components should differ in their solubility in the suspension medium of the preparations (water) by a factor of at least 10. This is also not proven by the Opponent in detail, the Opponent merely refers to D1 as such, noting *that this feature is fulfilled in the possibilities of combinations disclosed in D1*. There is obviously no need for further statements at this point that without any investigation on his own, this assertion can not be examined.

Finally, even the statements of the Opponent concerning feature D are not sufficiently substantiated (feature D = that the amount of solubilizing components is less than 0.1 mol %, referring to the amount of these substances, at which the point of solubilization or point of saturation of the covered droplets is reached). The technical feature "point of solubilization" which is important for an exact dosing of the components, is neither mentioned nor discussed in this context.

With respect to the dependent claims, the Opponent has practically made no statements which would enable the Patentee or the Opposition Division to finally judge on the asserted opposition ground without any investigations on their own.

Even the lengthy passages of the Opponent, that certain formulations of the patent are not understandable or not clear, do not represent an opposition ground, according to § 21 German Patent Law, and are thus simply superfluous.

In summary, the reasons for opposition do not go into the total patented teaching, and thus, the Opposition is formally inadmissible.

Consequently, the so-founded Opposition has to be rejected as inadmissible.

III. Foundation of the Opposition

Before individually discussing the documents D1-D5 cited by the Opponent, it has to be pointed out that the arguments presented by the Opponent are predominately based on assertions and statements which do not grapple with the features of the claims. At this point, it has to be stressed again that the opposition grounds are provided in §21 German Patent Law in total.

In D1, preparations are disclosed having an amount of a surface-active substance, which corresponds to 99 mol % of the amount of this substance, at which the point of solubilization of the droplets is reached. In contrast to the present invention, the amount of surface-active substance is chosen with full awareness that one approaches the point of solubilization, which is the amount at which the droplet would dissolve. Thus, with full awareness, a strain is put on the stability parameters, in order to optimize the penetration capability. As a result, preparations for the transport of active agents are obtained according to D1, which undergo an optimization of their penetration capability by adjusting the amount of surface-active substance near the point of solubilization.

The present invention is completely different. Here, the stressed preparations having an amount of solubilizing components of less than 0.1 mol % according to claim 1, show a high mechanical elasticity and deformability, although the person skilled in the art would not expect this due to the actually expected high stability.

The Opponent itself states in the opposition grounds on page 7, middle of paragraph III, that the feature Da)-amount of solubilizing components of less than 0.1 mol %, referring to the point of solubilization, is not disclosed in the prior art, nor is it obviously derivable.

Looking at Figure 1 and Figure 2 of the attacked patent, the difference between feature D1) and Db) can be recognized without further ado. According to Fig.2 (feature Db)) an increase of the amount of solubilizing components practically does not lead to any further change of the permeation resistance from a certain amount on. Such systems, which do not show any point of solubilization, are neither disclosed nor obviously derivable, in D1 or any of the documents D2-D5.

D1 does not provide any indication or teaching for a person skilled in the art to select the amount of solubilizing components in such a way that it is far away from the point of solubilization, i.e. less than 0.1 mol %, in order to optimize the penetration capability.

Consequently, D1 does not provide a relevant prior art, since it discloses a teaching which is opposite to the teaching of the present invention, namely to optimize the penetration capability of preparations, by working with an amount of solubilizing components near the point of solubilization up to 99 mol %.

Document D2 discloses on page 42, Fig. 5, a ternary phase diagram of any mixture of lecithin/lysolecithin/water at 52°C.

D2 does not provide any indication, how to adjust the amount of solubilizing components, in order to obtain an optimal penetration capability of active substance carriers, according to claim 1 of the present patent. D2 further does not provide any indication that the components should differ in solubility, for example in water, by a factor of 10. Furthermore, D2 discloses

a ternary phase diagram at 52°C, which cannot be transformed to the inventive systems, for the simple reason that these commonly require skin temperature of 32° C.

Thus, D2 is not suitable, neither alone, nor in any combination with documents D1, D3, D4 or D5, to seriously question novelty or inventive activity of the present patent.

Document D3 does not disclose preparations for application or for the transport of at least one active agent, in particular for medicinal or biological purposes, into and through barriers and constrictions like skins. Furthermore, D3 does not contain any indication that for the purpose of optimizing the penetration capability, at least two (physico-chemically) different components should be included, which differ in solubility in, for example, water, by a factor of at least 10, and that the amount of solubilizing components should be less than 0.1 mol %, referring to the amount of these substances, at which the point of solubilization of the covered droplets is reached, or this point of solubilization cannot be reached at all.

Consequently, D3 is not relevant, neither alone nor in combination with the other cited documents.

Documents D4 and D5 disclose the problems occurring while isolating lipids. According to D4, lecithin extracted from soybean oil is obtained as a mixture with certain fatty acids.

Disregarding the fact that D4 and D5 relate to a totally different technical field, and do not disclose any feature which is subject matter of the patent claims, one cannot derive any indication, neither from D4 nor D5, that these mentioned fatty acids amounts actually show solubilizing properties within the meaning of the invention, and that the amount thereof is less than 0.1 mol %, referring to the point of solubilization.

Thus, neither D4 nor D5 is relevant prior art.

Since none of the cited prior art documents anticipates or suggests, either alone or in combination, the subject matter of patent claim 1, also method claim 22, which comprises the features of claim 1, is based on a novel and inventive disclosure.

Thus, the Opposition has to be rejected as unfounded.

Signed by Dr. Stefan Michalski